IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG,	)	
Plaintiffs,	)	C.A. No. 12-1032-GMS
v.	)	
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC,	)	
Defendants.	)	

DEFENDANTS WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT(US), LLC, AND WARNER CHILCOTT PLC'S
OPENING CLAIM CONSTRUCTION BRIEF

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Plaintiffs ("Bayer") allege that the sale of LO LOESTRIN FE, an oral contraceptive made by Defendants ("Warner Chilcott"), infringes U.S. Patent No. 5,980,940 ("the '940 patent"). Bayer further alleges statutory interference between the '940 patent and Warner Chilcott's U.S. Patent No. 7,704,984 ("the '984 patent"). The parties have not identified any terms of the '984 patent requiring construction. Accordingly, Warner Chilcott submits this Opening Brief to address the seven disputed claim terms in the '940 patent. *See* D.I. 58 (Joint Claim Chart).

I. INTRODUCTION

The '940 patent claims a pharmaceutical combination, or "packaging unit," of specifically-ordered daily hormone doses—something one might commonly recognize as a blister pack of oral contraceptive tablets. But Bayer did not invent the first oral contraceptive, and the '940 patent does not claim the first oral contraceptive. Accordingly, to obtain the '940 patent, Bayer had to distinguish its oral contraceptive regimen from prior art oral contraceptives. In doing so, Bayer utilized a number of vague, relative, and subjective claim terms such as

- "*high* contraceptive reliability,"
- "*low* incidence of follicular development,"
- "*satisfactory* cycle control," and
- "*reliable* avoidance of intracyclic menstrual bleeding and undesirable side effects."

While claim terms generally and presumptively carry their plain and ordinary meaning, such terms *did not have* a plain and ordinary meaning at the time of the invention, and by themselves do not have sufficient clarity to delineate the scope of the '940 patent's claims.

If the limitations noted above are construable at all, the Court must rely on the intrinsic evidence of record, which at least provides some guidance as to the meaning of these relative terms. As explained below, the inventors represented in the specification and prosecution history of the '940 patent that prior art oral contraceptives lacked "high contraceptive reliability," "low incidence of follicular development," "satisfactory cycle control," and "reliable avoidance of

intracyclic menstrual bleeding and undesirable side-effects"—and that the claimed regimen of the '940 patent provided such characteristics "for the first time." Only by relying upon these alleged distinctions over the prior art was Bayer was able to obtain the '940 patent.

Consistent with the intrinsic evidence, including Bayer's affirmative representations to the U.S. Patent & Trademark Office ("PTO"), Warner Chilcott's constructions define these relative terms in relation to the prior art discussed in the specification. For the most part, these constructions mitigate the indefiniteness problems that would arise if these terms were construed according to Bayer's proposals, which would only further confound the scope of the claims.[1] In contrast, Bayer's constructions find no support in the specification and are inconsistent with the positions Bayer took during prosecution to obtain the '940 patent, and should be rejected.

Warner Chilcott also seeks construction of one claim term relating to the order of administration of the claimed oral contraceptive—"between these two hormone components"—to give effect to this term's plain and ordinary meaning, from which Bayer seeks to depart.

II. BACKGROUND

A. Legal Standards

The purpose of claim construction is "to assign a fixed, unambiguous, legally operative meaning to the claim." *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004). For each claim term, the construction should provide clarity and "aid the court [] in understanding the term as it is used in the claimed invention." *See Funai Elec. Co. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010).

[1] While Warner Chilcott proposes constructions to mitigate several indefiniteness problems, no claim construction could cure all of them—and Bayer's proposed constructions only exacerbate the indefiniteness situation. At the appropriate time, Warner Chilcott will seek leave to move for summary judgment on one or more grounds of indefiniteness. To the extent the claims may be construed to avoid indefiniteness, Warner Chilcott advances those constructions here.

The Court must begin its analysis with the claim language, read in light of the intrinsic evidence. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The claims are construed through the eyes of the "person of ordinary skill" in the art (POSA) at the time of the invention. *Phillips*, 415 F.3d at 1313.

The POSA "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification . . . . and the prosecution history." *Id.* (citations omitted). The specification "is always highly relevant . . . . Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir. 1996)). While there is a presumption that claim terms are to be given their plain meaning, *Phillips*, 415 F.3d at 1312-13, claim language by itself often lacks sufficient clarity to ascertain the scope of the claims, making it especially necessary to consult the specification in those cases. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005).

The court must also consider the prosecution history, which "provides evidence of how the PTO and the inventor understood the patent" and "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317 (citing *Vitronics*, 90 F.3d at 1582). Courts may also rely on extrinsic evidence, including expert testimony, dictionaries, and learned treatises, but such evidence is less significant than the intrinsic record in construing claim terms. *Id.*

B. The '940 Patent

The '940 patent contains ten claims. Claim 1 is the only independent claim and is drawn to a pharmaceutical combination comprising a "packaging unit" of specified and ordered

hormone components; the remaining claims depend from claim 1. *Id.* col. 7-8. Claims 7 through 9 are drawn to contraceptive methods utilizing the claimed pharmaceutical combination.

As reflected in the claims, the ’940 patent is directed to a combination oral contraceptive regimen with multiple, ordered phases of hormone administration. In the *first phase*, beginning with the first day of the cycle, a *combination* of estrogen and progestin (gestagen) is administered on a daily basis, over 23 or 24 days, in daily dosage units. ’940 patent, col. 3, ll.54-57; col. 1, ll.21-31, col. 5, ll.31-48. After the first phase, there is a placebo phase, comprising administration of 1 or 2 days of blank “placebo” tablets, free of active ingredients. *Id.* col. 3, ll.50-54, 57-59; col. 5, ll.35-48; col. 1, ll.21-31.

Then, after the placebo phase, there is the *second phase* of hormone administration, in which *estrogen-only* tablets are administered daily over 2-4 days. *Id.* col. 3, ll.59-62; col. 1, ll.21-31; col. 5, ll. 31-48. This administration scheme is depicted in the ’940 patent as shown at ’940 patent col. 5, ll.34-49 (depicted at right).

EXAMPLES

Day	1	2	3	4	5	6	7	
Composition	C	C	C	C	C	C	C	
Day	8	9	10	11	12	13	14	
Composition	C	C	C	C	C	C	C	
Day	15	16	17	18	19	20	21	
Composition	C	C	C	C	C	C	C	
Day	22	23	24	25	26	27	28	
Composition	C	C	C	P	P	E	E	Example 1
	C	C	P	P	E	E	E	Example 2
	C	C	C	P	E	E	E	Example 3
	C	C	P	E	E	E	E	Example 4

Day = Day of the menstrual cycle, day 1 is the first day of bleeding
C = combination of estrogen and gestagen (= first hormone component)
E = estrogen (= second hormone component)
P = placebo or indications of a blank pill day.

As the depiction shows, blank “placebo” tablets of the placebo phase are provided *between* the first phase of hormone administration (combination tablets) and the second phase of hormone administration (estrogen-only tablets). *See id.* Abstract; col. 1, ll.9-12, 15-29; col. 3, ll.50-62; col. 4, ll.19-22, 28-35; col. 5, ll.54-col.6, ll.8; col. 6, ll.9-14, 22-27, 32-38.51-62. At no point does the specification suggest a placebo phase that does not immediately follow the first hormonal phase and immediately precede the second hormone phase. The patent prefers an estrogen dose of 15-25 micrograms (“mcg”) of ethinylestradiol (“EE”) in the first phase and 2-40

mcg EE in the second phase. *Id.* col. 4, ll.48-col. 5, ll.13. Finally, the patent lists eight progestins, and of those, "emphasizes" gestodene and levonorgestrel. *Id.* col. 4, ll.36-54; col. 5, ll.23-24.

The specification of the '940 patent describes the oral contraceptive regimen covered by the claims as having "advantages . . . *compared to the previously described* [oral contraceptive] *preparations* [discussed in the specification of the '940 patent], especially those with a daily ethinylestradiol dose of less than 30 mcg and those with a prolonged pill-free interval." *Id.* col. 6, ll.9-14 (emphasis added). These "advantages" included "[a] significantly lower frequency of follicular development . . . greater contraceptive reliability," "considerably improved cycle control" and in particular, "[b]etter cycle control, specifically from the first intake cycle." *Id.* col. 6, ll.15-39. Thus, as set forth in the specification of the '940 patent, the benchmark against which the invention is measured is prior art hormone-based oral contraceptives, not some other non-hormonal contraceptive method or population.

During prosecution, the Examiner initially rejected the claims of the '940 patent as obvious over the prior art. July 20, 1998 Office Action, BHC-LOLO-00000074-80, at 2-4. To overcome this rejection, the applicants amended claim 1 to add the "whereby" clause in which the applicants explained that through its "low estrogen content and low total hormone content," the claimed oral contraceptive regimen:

> provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects." Jan. 20, 1999 Amendment, BHC-LOLO-00000087-93, at 2 (amending claim 1).

The applicants further explained that these features *distinguished* the claimed regimen from prior art oral contraceptives described in the specification of the '940 patent, and that such differences warranted a patent:

> ***The deficiencies of the prior art multiphasic combination preparations*** including those disclosed in Pasquale, are discussed in the specification . . . ***and contrasted with the superior results of the present regimen*** in particular that it provides a contraceptive effect whereby the low effective estrogen content and low total hormone content provides ***high contraceptive reliability***, ***low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. . .***
>
> There is no teaching in the cited prior art . . . whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. ***The present invention provided such a low-dose, contraceptively effective pharmaceutical preparation for the first time***. *Id.* at 5 (emphasis added).

After amending the claims and explaining that the claimed invention provided an oral contraceptive with "high contraceptive reliability," "low incidence of follicular development," "satisfactory cycle control," and "reliable avoidance of intracyclic menstrual bleeding and undesirable side effects" "for the first time," the inventors obtained the '940 patent.

C. Disputed Claim Terms

All of the disputed terms appear in claim 1 of the '940 patent, and are incorporated into the remaining claims through dependency: (1) "high contraceptive reliability"; (2) "low incidence of follicular development"; (3) "satisfactory cycle control"; (4) reliable avoidance of intracyclic menstrual bleeding"; (5) "reliable avoidance of . . . undesirable side effects";[2] (6) "effective estrogen content"; (7) "between these two hormone components."

The first six of these terms appear in "whereby" clause of claim 1 (the final clause of that claim). Each of these terms raises at least two indefiniteness concerns: (i) the standard against

[2] Bayer proposes that these first five terms should be lumped together into a single claim term. But efficacy, follicular development, cycle control, and side effects are all distinct concepts. *See* '940 patent at 1:51-59 (distinguishing contraceptive reliability, cycle control, and side effects); *id.* at 6:9-21 (distinguishing follicular development and contraceptive efficacy); Simon Decl. ¶¶ 17, 29. There is no basis for conflating these different concepts into a single term.

which the limitation is measured; and (ii) the analytical tool by which the measurement is made. Warner Chilcott's proposed constructions solve the first concern by relying on the same standard Bayer set forth in the specification and relied on during prosecution—judging the claimed invention against the prior art cited in the '940 patent itself. The second concern is more problematic, and Bayer has not identified any commonly accepted analytical tool or process by which any of these measurements should be made. As set forth below, at least with regard to contraceptive efficacy, Warner Chilcott proposes the use of the industry standard Pearl Index.

D. Person of Ordinary Skill In The Art

For claim construction, Warner Chilcott assumes a POSA is a physician with several years of experience prescribing oral contraceptives, or a person with an advanced degree in physiology, pharmacology, or pharmaceutical science who studied oral contraception specifically for years.

III. ARGUMENT

A. The Six Disputed Terms in the "Whereby" Clause of Claim 1 Must Be Construed in Light of the Intrinsic Evidence to Distinguish the Claimed Oral Contraceptive from the Prior Art.

As explained below, the six terms in claim 1's "whereby" clause should be construed as Warner Chilcott proposes because the intrinsic evidence compels such constructions, and, absent such constructions, these terms would be indefinite.

	Claim Term	Warner Chilcott's Proposed Construction	Bayer's Proposed Construction
1	**"high contraceptive reliability"**	"contraceptive efficacy, measured using the Pearl Index, greater than that of each and every prior art oral contraceptive regimen identified in the '940 patent's specification"	"high contraceptive reliability as compared to a healthy population of women not using hormonal birth control"

"*High contraceptive reliability*" should be construed to mean "contraceptive efficacy, measured using the Pearl Index, greater than that of each and every prior art oral contraceptive regimen identified in the '940 patent's specification."

"High contraceptive reliability" is not a term of art in the field of contraception, nor has it ever been. Simon Decl. ¶ 11. The term does not have a singular, commonly accepted meaning, and is instead a vague, subjective, relative phrase, which different people would understand in different ways. *Id.* While a POSA would have understood that "high" contraceptive reliability conveys that an oral contraceptive causes relatively few unintended pregnancies, it would have been unclear *just how few* or, equally important, in comparison to what standard this assessment should be made. *Id.* Because this subjective term does not provide an objective standard by which to determine when an oral contraceptive could be said to have "high" contraceptive reliability, the term by itself is insufficient to delineate the scope of the claims, making it critical to consult the specification. *See Datamize*, 417 F.3d at 1350-51; *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005).

The '940 patent's specification does provide some guidance. It notes that the "advantages" of the claimed regimen over the prior art oral contraceptives mentioned in the specification include "greater contraceptive reliability." '940 patent col. 6, ll.9-18. In light of this statement, and in the absence of any other guidance in the specification, the term "high contraceptive reliability" must be construed to mean "contraceptive efficacy greater than that of each and every prior art oral contraceptive regimen identified in the '940 patent's specification." *See, e.g., Chimie*, 402 F.3d at 1380 (where meaning of claim term is provided solely by reference to characteristics of the prior art, it is proper "to limit the scope of this relative term to the only disclosure on the subject made in the patent.").

The prosecution history of the ’940 patent confirms this construction. As discussed above, during prosecution, the Examiner initially rejected the claims of the ’940 patent as obvious. July 15, 1998 Office Action at 2-4. *Id.* To overcome this rejection, the applicants amended claim 1 to add the “whereby” clause in which the applicants explained that the claimed oral contraceptive regimen provides “high contraceptive reliability” along with other characteristics. Jan. 20, 1999 Amendment at 2 (amending claim 1). The applicants further explained that this characteristic *distinguished* the claimed regimen from prior art oral contraceptives described in the specification of the ’940 patent; that the claimed regimen showed “superior results” over the prior art, “in particular that it provides a contraceptive effect whereby the low effective estrogen content and low content hormone content provides *high contraceptive reliability*”; and that the claimed regimen provided this reliability “*for the first time*.” *Id.* at 5 (emphasis added).

The inventors thus made clear that they understood “high contraceptive reliability” to mean a degree of contraceptive efficacy that had not been previously provided by the prior art oral contraceptives identified in the specification of the ’940 patent. Consistent with this understanding, “high contraceptive reliability” should be construed to mean “contraceptive efficacy greater than each and every prior art oral contraceptive identified in the specification of the ’940 patent.” *See, e.g.*, *Phillips*, 415 F.3d at 1317 (“the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution.”). Bayer’s proffered construction would allow it to do the very thing courts routinely reject—construing the claims narrowly during prosecution only to turn around and broaden them during litigation. *See White v.*

Dunbar, 119 U.S. 47, 51 (1886) (rejecting patentee's attempt to treat claims limitations as a "nose of wax which may be turned and twisted in any direction").

Finally, although neither the specification nor the prosecution history describes how to measure contraceptive efficacy for purposes of the claims, a POSA would have understood that the Pearl Index was widely recognized as the common measure of contraceptive efficacy. Simon Decl. ¶ 12. Abundant prior art, including at least one publication by a named inventor of the '940 patent, corroborates that point.[3] Accordingly, the Court should construe "high contraceptive efficacy to mean "contraceptive efficacy, measured using the Pearl Index, greater than that of each and every prior art oral contraceptive regimen identified in the '940 patent's specification."

Bayer proposes that "high contraceptive reliability" be defined as "high contraceptive reliability as compared to a healthy population of women not using hormonal birth control." But Bayer's proposed construction finds no support in the intrinsic evidence, which nowhere suggests using a "healthy population of women not using hormonal birth control" as a baseline to assess the meaning of "high" contraceptive reliability. Rather, as discussed above, the intrinsic evidence makes clear that "high contraceptive reliability" should be understood by reference to, and in contrast to, prior art oral contraceptives.

Bayer's construction should also be rejected because it is not clear what it even means. "High" contraceptive reliability has no singular, commonly understood meaning in the context of women who do not use hormonal birth control, and so using that as a frame of reference would be meaningless. Bayer does not explain *how* a comparison to such a population would elucidate the meaning of "high contraceptive reliability," or precisely how this "comparison" would even

[3] *See, e.g.*, Dusterberg, B., Brill, K. *Clinical acceptability of monophasic gestodene* (1990) American Journal of Obstetrics and Gynecology, Vol. 163, No. 4, part 2, 1398-1404, at 1400-01 (WC_DEL_00034904-12) (reporting "contraceptive reliability" in terms of Pearl Index).

work. Nor does Bayer's proposal explain *who* the so-called "healthy population of women" would even consist of. Do these women use *any* birth control, and if so, what kind? How old are these women? To what degree, if any, are they sexually active? The answers to these and other questions would have major ramifications for the degree to which this "healthy population of women" was at risk of becoming pregnant.[4] Simon Decl. ¶ 31. Yet, Bayer's construction answers none of these questions, rendering Bayer's construction itself indefinite. *See Geneva Pharm. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (rejecting proposed construction that would itself be indefinite).

	Claim Term	**Warner Chilcott's Proposed Construction**	**Bayer's Proposed Construction**
2	**"low incidence of follicular development"**	"a lesser incidence of follicular development than the incidence of follicular development with each and every prior art oral contraceptive regimen identified in the '940 patent's specification."	"low incidence of follicular development as compared to a healthy population of women not using hormonal birth control"

"Low incidence of follicular development" should be construed to mean "a lesser incidence of follicular development than the incidence of follicular development with each and every prior art oral contraceptive regimen identified in the '940 patent's specification."

"Low incidence of follicular development" is not a term of art in the field of oral contraception, nor has it ever been. Simon Decl. ¶ 13. The term does not have a singular, commonly understood meaning, and is instead a subjective, relative phrase whose meaning to persons of ordinary skill in the art would differ. *Id.* While a POSA would have understood that "low" incidence of follicular development was intended to mean a relatively infrequent incidence

[4] For example, sexually active women of reproductive age using non-hormonal methods of sterilization or a copper IUD would have a lower risk of pregnancy than if they used a condom, and a far lesser risk of pregnancy than if they used no contraception at all. Simon Decl. ¶ 31.

of the development of ovarian follicles, *see, e.g.*, '940 patent col. 3, ll.25-49; col. 4, ll.19-27, it would have been unclear *just how infrequent*. Simon Decl. ¶ 13. As this relative term does not provide an objective standard by which to determine when an oral contraceptive has a "low" incidence of follicular development, the term by itself is insufficient to delineate the scope of the claims. *See Datamize*, 417 F.3d at 1350-51.

The Court must therefore look to the specification for guidance. Here, the specification notes that the "advantages" of the claimed regimen over the prior art oral contraceptives mentioned in the specification includes "a significantly lower frequency of follicular development in the user." '940 patent col. 6, ll.9-17; *see also id.* col. 3, ll.25-49, col. 3, ll.66 - col. 4, ll.7. In light of this statement, and in the absence of other guidance in the specification, the term "low incidence of follicular development" should be construed to mean "a lesser incidence of follicular development than the incidence of follicular development with each and every prior art oral contraceptive regimen identified in the '940 patent's specification."[5]

The prosecution history of the '940 patent reinforces this conclusion. As discussed above, to overcome an obviousness rejection, the inventors amended the claims of the '940 patent to add the requirement that the claimed regimen have a host of characteristics, including a "low incidence of follicular development," and explained that the claimed regimen's "low incidence of follicular development" distinguished that regimen from the prior art. *Supra* pp. 4-6. Thus, the inventors clearly understood "low incidence of follicular development" to mean a less follicular

[5] While Warner Chilcott proposes this construction, it will ultimately seek leave to file for summary judgment to challenge this claim term as indefinite. Warner Chilcott's construction seeks to resolve the ambiguity of the relative, subjective term "low." But the other part of this term—"incidence of follicular development"—is indefinite, because the '940 patent does not define a threshold as to when "follicular development" can be said to have occurred, and different scientists used different, conflicting thresholds at the time of the purported invention. *See, e.g.*, Simon Decl. ¶¶ 14-16.

development than seen with the prior art oral contraceptives identified in the specification.

Bayer proposes that "low incidence of follicular development" means "low incidence of follicular development as compared to a healthy population of women not using hormonal birth control." D.I. 58. But that proposed construction is contrary to the intrinsic evidence, which makes clear that the inventors understood "low" incidence of follicular development by reference to, and in specific contrast to, *prior art oral contraceptives*, not a so-called "healthy population of women not using hormonal birth control."

It is also unclear what Bayer's construction would even mean. "Low incidence of follicular development" has no singular, commonly understood meaning in the context of women who do not use hormonal birth control, and Bayer does not explain *how* a comparison to a "healthy population of women not using hormonal birth control" would even work, much less elucidate the meaning of "low incidence of follicular development." Moreover, as discussed above, Bayer's construction is indefinite as to whom the "healthy population of women not using hormonal birth control" would even be. *See supra* p. 9.

	Claim Term	**Warner Chilcott's Proposed Construction**	**Bayer's Proposed Construction**
3	**"satisfactory cycle control"**	"a lower incidence of intracyclic menstrual bleeding (*i.e.*, any bleeding occurring outside the hormone-free interval) than the incidence of such bleeding with each and every prior art oral contraceptive regimen identified in the '940 patent's specification"	"satisfactory cycle control as compared to a population of healthy women not using hormonal birth control"
4	**"reliable avoidance of intracyclic menstrual bleeding"**	same as construction as for "satisfactory cycle control"	"reliable avoidance of intracyclic menstrual bleeding as compared to a population of healthy women not using hormonal birth control"

"*Satisfactory cycle control*" and "*reliable avoidance of intracyclic menstrual bleeding*" should be construed to mean "a lower incidence of intracyclic menstrual bleeding (any bleeding occurring outside the hormone-free interval) than with each and every prior art oral contraceptive regimen identified in the '940 patent's specification."

The specification defines "cycle control" as "incidence of intracyclic menstrual bleeding." '940 patent, col. 1, ll.52-59. "Intracyclic menstrual bleeding," in turn, would have been understood by a POSA to refer to any vaginal bleeding that occurs during the period in which tablets containing active hormones are taken, *i.e.*, bleeding that occurs outside of the hormone-free interval, including "breakthrough bleeding and spotting."[6]

But without more guidance, a POSA would not have known what was intended by "*satisfactory* cycle control" or "*reliable* avoidance of intracyclic menstrual bleeding," because "satisfactory" and "reliable" are vague, subjective, relative terms about which different persons would have had different ideas. Simon Decl. ¶¶ 18-24. Thus, by themselves, these terms do not sufficiently delineate the scope of the claims. *See Datamize*, 417 F.3d at 1350-51.

The intrinsic evidence, however, does provide guidance as to the meaning of these terms. The specification notes that the "advantages" of the claimed regimen over the prior art oral contraceptives mentioned in the specification includes "better" and "improved" cycle control. '940 patent col. 6, ll.9-14, 22-39. And the prosecution history reveals that, in overcoming an obviousness rejection, the inventors amended the claims of the '940 patent to add the requirement that the claimed regimen have "satisfactory cycle control" and "reliable avoidance

[6] Simon Decl. ¶ 19; '940 patent col. 3 ll.45-49 ("cycle control with reliable avoidance of intracyclic menstrual bleeding such as breakthrough bleeding and 'spottings'"); Rosenberg et al., *Oral Contraceptives and Cycle Control: A Critical Review of the Literature*, 8 Advances in Contraception, 35-45 (1992) (WC_DEL_00036281-92) (defining "cycle control" as "[c]ontrol of spotting and breakthrough bleeding and absence of withdrawal bleeding").

of intracyclic menstrual bleeding," and that the inventors represented that such characteristics distinguished the claimed regimen from the prior art, in that the claimed regimen provided such characteristics "for the first time." *See supra* pp. 4-6 (discussing Jan. 20, 1999 Amendment pp. 2, 5). In light of this intrinsic evidence, "satisfactory cycle control" and "reliable avoidance of intracyclic menstrual bleeding" should be construed to mean "a lower incidence of intracyclic menstrual bleeding (any bleeding occurring outside the hormone-free interval) than with each and every prior art oral contraceptive regimen identified in the '940 patent's specification."

Bayer's proposed constructions should be rejected, as there is no support in the intrinsic evidence for defining these terms by reference to a fictitious "healthy population of women not using hormonal birth control." Moreover, it is not clear what Bayer's constructions would even mean, as the concept of cycle control is not applicable outside the context of hormonal contraceptive use, *see* Simon Decl. ¶ 24, and Bayer's construction leaves unclear who would comprise the "healthy population of women not using hormonal birth control." *Supra* p. 9.

	Claim Term	**Warner Chilcott's Proposed Construction**	**Bayer's Proposed Construction**
5	**"reliable avoidance of . . . undesirable side effects"**	"a lower incidence of each undesirable side effect than is caused by each and every prior art oral contraceptive regimen identified in the '940 patent's specification"	Reliable avoidance of undesirable side effects as compared to a population of healthy women not using hormonal birth control

"*Reliable avoidance of . . . undesirable side effects*" should be construed to mean "a lower incidence of each undesirable side effect than is caused by each and every prior art oral contraceptive regimen identified in the '940 patent's specification." As with "reliable avoidance of intracyclic menstrual bleeding," the specification and prosecution history of the '940 patent compel this construction by making clear that the inventors understood "reliable avoidance" to mean that the oral contraceptive avoided undesirable side effects to a greater degree than prior

art oral contraceptives. *See supra* pp. 4-6. Moreover, without Warner Chilcott's construction, this subjective, vague term would be indefinite, as the words "reliable avoidance" by themselves are insufficient to ascertain the scope of the claims of the '940 patent. Simon Decl. ¶ 27.

As with its other proposed constructions, Bayer proposes that this term be understood "as compared to a healthy population of women not using hormonal birth control." But as discussed above, the intrinsic evidence nowhere suggests using such a population in defining the vague, subjective, relative terms of the '940 patent, including "reliable avoidance," and it is unclear who exactly this population would consist of. Furthermore, considering whether an oral contraceptive "reliably avoids" undesirable side effects by comparison to a "healthy population of women" not using any form of birth control makes no sense. A side effect is the result of a drug or therapy—it is not an effect that one experiences while *not using* a drug or therapy. *See Stedman's Medical Dictionary*, 25th Ed. (1990) at 1416, WC_DEL_00036658 (defining "side effect" as "a result of drug or other therapy in addition to or in extension of the desired therapeutic effect; usually but not necessarily, connoting an undesirable effect."). Thus, by definition, an oral contraceptive could not "reliably avoid" side effects to a greater extent than healthy women not using contraception, as those women *by definition* do not experience side effects.

	Claim Term	**Warner Chilcott's Proposed Construction**	**Bayer's Proposed Construction**
6	**"effective estrogen content"**	"Daily dose of estrogen, equivalent to at least 15 mcg EE in the combination tablets, and equivalent to at least 2 mcg EE in the estrogen-only tablets"	"Daily dose of estrogen equivalent to no more than 40 mcg of ethinyl estradiol."

The '940 patent states that the object of the alleged invention is "to make available a combination preparation with an estrogen content that is ***as low as possible*** in each individual dosage unit." '940 patent col. 3, ll.40-49 (emphasis added). In light of that objective, and given the remainder of the specification of the '940 patent, "effective estrogen content" should be

construed to mean "daily dose of estrogen, equivalent to at least 15 mcg EE in the combination tablets, and equivalent to at least 2 mcg EE in the estrogen-only tablets."

The '940 patent describes an oral contraceptive with two hormone components: a "first" hormone component (combination tablets of estrogen and progestin) and a "second" hormone component (estrogen-only tablets). *See supra* pp. 4-5. For the first hormone component, the '940 patent expresses a preference for estrogen dose in the range of 15-25 mcg ethinyl estradiol (EE). '940 patent col. 4, ll.58-64.

Given the objective of the patent to provide a daily estrogen content that was "as low as possible in *each* individual dosage unit," the inventors would have preferred and described the use of an estrogen dose of *less* than 15 mcg EE for the first hormone component if they believed that such an estrogen content would be "effective." Indeed, it would have made no sense to prefer an estrogen content that was *higher* than the lowest daily estrogen dose that the inventors believed was possible, as doing so would have run counter to the '940 patent's central objective of providing "an estrogen content that is ***as low as possible*** in each individual dosage unit." '940 patent col. 3, ll.40-49.

Furthermore, the specification provides other indications that the inventors did not believe that doses below 15 mcg EE would be "effective," noting, for example, that the "risk of pregnancy [wa]s . . . high, especially in the case of intake errors below the 20 mcg ethinylestradiol preparations," and that contraceptive efficacy was "jeopardized" with prior art preparations containing a daily dose of less than 20 mcg EE. '940 patent, col. 2, ll.61-66; col. 3, ll.31-39. Moreover, *nowhere* in the specification of the '940 patent did the inventors describe using a daily estrogen dose of less than 15 mcg EE in combination phase. Thus, for purposes of the combination phase, "effective estrogen content" should be construed to mean a minimum

daily dose equivalent to 15 mcg EE. *See, e.g.*, *Phillips*, 415 F.3d at 1323 (advising court to read specification to determine "whether the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive"); *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims . . . even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.")

By contrast, the '940 patent prefers a much lower daily EE dose in the *second* (estrogen-only) component of the claimed regimen—down to 2 mcg—revealing that when the inventors believed they *could* provide a daily estrogen dose below 15 mcg EE, they so specified. '940 patent col. 5, ll.9-13. A POSA would have understood that there was a distinction between the claimed regimen's first hormone component (combination phase), which lasted for 23-24 days, and the much shorter second hormone component (estrogen-only phase), which lasted only 2-4 days. The 2-4 days of estrogen-only tablets replaced what had typically been *blank* tablets containing *no estrogen* in "21/7" regimens, and thus a POSA would have understood that a lower estrogen dose could be used in the second hormone component and still be contraceptively effective. Simon Decl. ¶ 35. "Effective estrogen content" should therefore be construed to mean "daily dose of estrogen, equivalent to at least 15 mcg EE in the combination tablets, and equivalent to at least 2 mcg EE in the estrogen-only tablets."

Bayer argues that "effective estrogen content" should be construed to mean a "daily dose of estrogen equivalent to no more than 40 mcg of ethinyl estradiol," but that construction is untenable. The specification provides no indication that the inventors intended 40 mcg EE to be an upper limit on effective doses, and there is no reason why dosages greater than 40 mcg EE

would not be effective when doses of 40 mcg EE *would* be effective. Indeed, the specification makes clear that *lowering*—not increasing—estrogen dose, threatens contraceptive efficacy (and cycle control). *See, e.g.*, '940 patent col. 2, ll.59-61. Moreover, the construction overlooks the fact that the inventors understood and intended the lowest "effective" dose to be 15 mcg EE in the combination phase, *see supra*—and implies that *any* amount of estrogen, however slight, would be "effective" so long as it is no more than the equivalent of 40 mcg EE, regardless of the number of pregnancies that occurred with the formulation containing that estrogen dose.

B. Claim Construction Is Necessary to Clarify One Term Relating to the Order of Administration of the Claimed Regimen in the '940 Patent.

Claim terms "are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312-13. But when there is a dispute over what that ordinary meaning is, construction is required. *O2 Micro International Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1361 (Fed. Cir. 2007). Here, Bayer's infringement contentions indicate that the parties dispute the ordinary meaning of "between these two hormone components."

	Claim Term	Warner Chilcott's Proposed Construction	Bayer's Proposed Construction
7	**"between these two hormone components"**	"immediately after a hormone component containing a combination of estrogen and progestin, and immediately before a hormone component containing estrogen only."	"After the first hormone component and before the second hormone component"

The claims and specification of the '940 patent provide that the "first hormone component" of the claimed regimen comprises a combination of an estrogen and a gestagen (progestin) in 23 or 24 daily units. '940 patent col. 7, ll.10-22, 25-26.[7] A POSA would have understood, based on plain meaning and the disclosures of the '940 patent, that as the *first*

[7] *See also id.* col. 1, ll.9-22; col. 3, ll.50-65; col. 5, ll.31-49; col. 5, ll.63-col. 6, ll.3.

hormone component, this component was administered *at the beginning*, *i.e.*, in the *first* 23 or 24 days, of the cycle. *Id.* col. 5 ll.33-48; col. 5, ll.63-col. 6, ll.3; col. 1, ll.9-26; col. 3, ll.49-63.

The claims and specification of the ’940 patent also provide that the “second hormone component” of the claimed regimen consists of estrogen-only tablets, in “4, 3, or 2 daily units.” ’940 patent, col. 7, ll.10-28 (claim 1); col. 1, ll.9-29; col. 3, ll.50-63; col. 5, ll.31-49; col. 5, ll.63-col. 6, ll.3. Consistent with the ordinary meaning of “second,” the specification makes explicit that this “second hormone” component comes *later than* the “first” hormone component. ’940 patent col. 5, ll.33-48; col. 5, ll.63-col. 6, ll.3; col. 3, ll.50-63 (noting that the first hormone component starts on the “first day of the cycle”).

Finally, a POSA would have understood that “between these two hormone components” means in the period between the *first* hormone component (combination of estrogen and progestin tablets) and the *second* hormone component (estrogen-only tablets). ’940 patent col. 5, ll.33-48; col. 5, ll.63-col. 6, ll.3; col. 3, ll.50-63; Simon Decl. ¶¶ 32-34. Therefore, “between these two hormone components” should be construed to mean “immediately after a hormone component containing a combination of estrogen and progestin, and immediately before a hormone component containing estrogen only.” *See, e.g.*, ’940 patent, col. 7, ll.10-35 (claim 1), col. 5, ll.33-48, col. 5, ll.63-col. 6, ll.3, col. 3, ll.50-63, col. 4, ll.19-35, col. 1, ll.9-26; Simon Decl. ¶¶ 32-34. And Bayer’s own depiction of the administrative scheme of the ’940 patent confirms Warner Chilcott’s construction. *See* D.I. 11 at 3 (illustration by Bayer in its Answering Brief in Opposition to Warner Chilcott’s Motion to Dismiss).

IV. CONCLUSION

For the foregoing reasons, Warner Chilcott respectfully requests that this Court construe the seven disputed claim terms according to Warner Chilcott’s proposed constructions.

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